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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,636	04/01/2004	Patrick T. Petruno	119204-007	1047

24573 7590 02/11/2009

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
02/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,636	PETRUNO ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,21-23,26 and 39-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,21-23,26 and 39-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 24 November 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 11, 12, 21-23, 26 and 39-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment to claim 11 requires "the optical system arranged to *modify* incident light from one of the control area and the target area" (emphasis added), which is not provided for by the instant specification. It is noted that that the instant specification teaches optical systems comprising a lens, chromatic prism, thin-film filter or diffractive grating at different places in the instant specification, but does not specifically teach modification of incident light using the optical system. Therefore the amendment does not have support in the specification as originally filed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11, 12, 21-23, 26 and 39-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites "a test strip having a test stripe, a control stripe and a receiving zone" in line 3 of the claim and in line 12 of the claim recite "a target area and a control area". It is unclear whether the test stripe and control stripe are the same as the target area and control area. Claim 11 also recites "a sample fluid" in line 5 of the claim and "a sample fluid" in line 8 the claim. It is unclear whether the "a sample fluid" recited in lines 5 and 8 of the claims are the same. Claim 11 further recites "the medium" in line 15 of the claim. There is insufficient antecedent basis for this limitation in the claim. It appears that "the medium" should be changed to "the test strip".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 11, 12, 21-23, 26, 39-41, 43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2002/0004246) in view of Crosby (US 6,217,744).

Daniels et al. teach a test system comprising: a test strip having a test stripe (anti-analyte 1 epitope B, Fig. 1; par. 218), a control stripe (control line, Fig. 1; par. 218), and a receiving zone (area under arrow pointing to test strip under sample is sample receiving zone, Fig. 1; sample pad, par. 219), the test strip being capable of generating a single response at the test strip and the control stripe subsequent to contact of a sample fluid in the receiving zone (par. 219 and 220), the test stripe containing a labeling substance that comprises first persistent fluorescent structures that emits light having a first frequency and second persistent fluorescent structures that emit light having a second frequency, wherein each of the first persistent fluorescent structures is attached to a substance that is capable of binding the first structure to a target analyte after a sample fluid containing the target analyte is applied to the receiving zone(each detection reagent is associated with a nanocrystal having a distinct emission peak and nanocrystal is a persistent fluorescent structure, par. 207; capture and control reagents bind the first and second structures and are present in a chromatographic medium therefore the first and second nanocrystal structures are present in a medium, par. 201; emission peak of nanocrystal incorporated into control is distinct from that exhibited by nanocrystals of the first detection reagent therefore first and second nanocrystals emit at different frequencies, par. 198);

a light source positioned to illuminate a target area and a control area on the medium (par. 213);

a first photodetector positioned to measure light of the first frequency originating from the target area of the medium (multiple detectors for each light emission frequency, par. 214);

a second photodetector positioned to measure light of the second frequency originating from the control area, wherein a signal from the second photodetector indicating an intensity above a threshold level indicates that the sample has passed through the target area (separate detector for each detection region with a different emission frequency, par. 214; control region has a different emission frequency than detection region, par. 198; detection of nanocrystals in the control region occurs in the presence or absence of analyte and therefore indicates that the sample has passed through the medium, par. 242); and

an optical system positioned in a light path between the light source and the first and second photodetectors, arranged to modify incident light from the control and target areas (par. 171).

Daniels et al. fail to teach the first and second photodetectors and medium contained in a single-use module.

Crosby teaches a photodetector and test strip necessary for optical detection contained in a single use module (optical components and porous membrane are part of the disposable device, optical components comprise the photodetector, col. 5, lines 64-

col. 6, line 13), in order to provide a self powered device that resists corrosion and degradation.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the test system of Daniels et al., the photodetectors and medium necessary for optical detection contained in a single use module as taught by Crosby, in order to provide small, point of care diagnostic tests that are small in size and produces a fast quantitative or qualitative result with increased reliability. Although Crosby does not specifically teach two photodetectors or an optical system, it would have been obvious to include all photodetectors and components necessary for detection using the photodetectors as taught by Daniels et al. as necessary for detection in the single use device taught by Crosby.

With respect to claims 12, 21 and 22, Daniels et al. fail to teach a reusable module with a user interface indicating an electrical test result.

Crosby teaches the reusable module implementing a user interface capable of indicating a test result on a display (console is the information gathering and storage system and has a display screen to display results from the disposable device, col. 7, lines 37-50) and the test signals are electrical signals (col. 7, lines 14-25).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the test system of Daniels et al., a user interface that displays electrical test signals on a display as taught by Crosby, in order to provide small, point of care diagnostic tests that are small in size and produces a fast quantitative or qualitative result with increased reliability.

With respect to claim 23, Daniels et al. teach the first and second persistent fluorescent structures comprising quantum dots (par. 198 and 79).

Regarding claim 26, Daniels et al. teach the medium comprising a lateral-flow strip for performing a binding assay (par. 200-201) and the target area containing an immobilized substance that binds to and holds the complex including one of the first persistent structures and the target analyte (par. 200-201; capture reagent binds to the detection complex, par. 189; detection complex comprises analyte and nanocrystal, par. 137-139; capture reagent is in a capture region, par. 115).

With respect to claims 39 and 40, Daniels et al. teach the second persistent structures bind to the control strip (control ligands are in a control region, par. 115; control ligands bind to second persistent structures that have an emission frequency different from that in the capture region, par. 198). Daniels et al. also teach a first and second color filter corresponding to the first and second photodetector that transmit the first and second frequencies, respectively (multiple detectors are present, one for each region, and each has a bandpass filter for detecting a narrow wavelength range corresponding to the nanocrystal emission wavelength in the capture and control regions, par. 214).

With respect to claim 41, Daniels et al. teach the control area containing an immobilized substance that binds and retains the labeling substance (par. 26 and 38).

Regarding claims 43 and 45, Daniels et al. teach the optical system comprising a chromatic prism (prism spectrally resolves colors, par. 172) or diffractive grating (par. 171 and 172).

2. Claims 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2002/0004246) in view of Crosby (US 6,217,744), as applied to claim 11, further in view of Cliche et al. (US 2003/0174743).

Daniels et al. in view of Crosby teach an optical system comprising a diffractive grating, but fail to teach an optical system comprising a thin-film filter.

Cliche et al. teach either a diffractive grating, thin-film filter (par. 69) or lenses (par. 89), in order to filter large optical bandwidths.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the system of Daniels et al. in view of Crosby, an optical system comprising a thin-film filter as taught by Cliche et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent optical modification technique and since the same light signal would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Response to Arguments

3. Applicant's arguments filed 24 November 2008 have been fully considered but they are not persuasive. Applicant argues that Daniels, Crosby and Holmes do not teach an optical system positioned in a light path between the light source and at least one of the photodetectors arranged to modify incident light from the control or target area. Applicant's argument is not persuasive because as discussed above, Daniels teaches chromatic prisms and diffractive gratings that pass light from the control and

target areas to the photodetectors and are therefore modify the signal between the light source and the photodetectors. Holmes is removed from the rejection in light of applicant's amendment.

Conclusion

4. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
February 10, 2009